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The Patentability and Patent Term Extension of Lifesaving Drugs: A Deadly Mistake

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THE PATENTABILITY AND PATENT TERM EXTENSION OF LIFESAVING DRUGS: A DEADLY MISTAKE

JONATHAN L. MEZRICH*

I. INTRODUCTION	111
II. STATUTORY REFORMS.....	112
III. DRUG COMPANIES FAIL TO LIVE UP TO THEIR END OF THE BARGAIN	117
IV. THE AIDS DRUG: AN EXTREME EXAMPLE OF ABUSE	118
V. AZT — RECENT DEVELOPMENTS.....	119
VI. OTHER MANUFACTURERS ARE CHARGING SIMILARLY PHENOMENAL PRICES.....	121
VII. OTHER EXAMPLES.....	122
VIII. THE COSTS AND TESTING TIMES FOR DRUGS	123
IX. PROBLEMS CAUSED BY ALLOWING DRUG COMPANIES TO PATENT LIFE-SAVING DRUGS.....	125
X. CONCLUSION: POSSIBLE GOVERNMENTAL SOLUTIONS.....	127

I. INTRODUCTION

The field of pharmaceutical patents is one which has spurred much litigation. While pharmaceuticals have long been recognized as patentable, quite a few cases have been raised regarding the utility and safety of pharmaceuticals.¹ Though utility is clearly a necessary element of any patent, the safety requirement was added out of fear that a government patent would be perceived as a stamp of approval on the safety of the product.² The safety questions of pharmaceutical patents were largely laid along the wayside when the Food and Drug Administration (FDA) gained prominence and began to require consumer drug products to pass FDA tests.

The pharmaceutical business is dominated largely by two types of entities: large, research-intensive corporations, and the smaller "generic" drug "knock-off" artists. Because the former organizations have to put so much of their budget into research and development (R&D), a form of

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¹ See generally, Deborah H. Brand, *Utility in a Pharmaceutical Patent*, 39 FOOD DRUG COSMETIC L. J. 480 (1984); See also H.I. FORMAN, *THE LAW OF CHEMICAL METALLURGICAL AND PHARMACEUTICAL PATENTS* (1967).

² Utility is required under 35 U.S.C. § 101. The danger with utility of drugs involved the difficulty of separating the bona fide remedies from the snake oils and salves of charlatans. See Brand, *supra* note 1, at 483.

investment which is often akin to pouring money into a hole, the 17-year exclusive monopoly of a patent is often the only way such a company can remain profitable. However, because of a concern for public safety, all substances prepared for human consumption must be put through extensive testing by the FDA. This testing could take a long period of time, and it was feared that any substantial FDA tests would eat up the monopoly period, putting the development-oriented drug companies out of business.³ Companies might have a miniscule period of time in which to recoup their often phenomenal research investment before the generic drug manufacturers would come in and undercut the market with cheaper versions of the same drugs.⁴ Responding to lobbying efforts of large pharmaceutical companies, Congress enacted a series of statutes to address what legislators saw as "two unintended distortions of the 17-year patent term."⁵

II. STATUTORY REFORMS

In 1984, Congress revised the United States Code with two somewhat conflicting objectives: encouragement of expensive pharmaceutical research and availability of affordable consumer drugs.⁶

³ "The skyrocketing costs of new drug R&D are in fact foreclosing many small businesses and universities from commitments in pharmaceutical development." Brand, *supra* note 1, at 490.

⁴ Or so the pharmaceutical companies would like us to believe. It is more likely that brand names are more durable than this, especially in light of the large percentage of doctors making brand specific prescriptions. See Linda Snyder, *Prescribing for the Drug Stocks*, FORTUNE, Jan. 30, 1978, at 121, 122; discussed further in note 59 *infra*. Additionally, many old drugs are used in conjunction with the newer generics rather than being superseded by them. Further, some drug companies have engaged in tying their drugs with other companies' medical services, in an effort to "extend their patent-like rights." It remains to be seen whether this violates antitrust laws. *States Charge Sandoz with Drug Typing Scheme*, 59 ANTITRUST AND TRADE REG. REP., No. 1496, at 896 (1990).

⁵ *Eli Lilly and Co. v. Medtronic, Inc.*, 110 S.Ct. 2683, 2688 (1990). See also U.S.L.W. — Daily Edition, BNA, Inc., Aug. 27, 1990, which tracks the Eli Lilly decision.

⁶ Section 156 is the most pertinent statute in 35 U.S.C. and will be dealt with further. § 155, enacted Jan. 4, 1983, allowed for patent term extensions for certain stays of regulation approval.

[T]he term of a patent which encompasses within its scope a composition of matter or a process for using such composition shall be extended if such composition or process has been subject to a regulatory review by the Federal Food and Drug Administration . . . leading to the publication of regulation permitting the interstate distribution and sale of such composition or process and for which there has thereafter been a stay of regulation of approval imposed pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act . . . which stay was in effect on January 1, 1981, by a length of time to be measured from the date such stay of regulation of approval was imposed until such proceedings are finally resolved and commercial marketing permitted. . . .

"Under Federal law, a patent grant[s] to the patentee, his heirs or assigns, for the term of seventeen years, . . . the right to exclude others from making, using or selling the invention throughout the United States.

§ 155A (a) allows for new drug product patent restorations,

[I]f during the regulatory review of the product by the Federal Food and Drug Administration —

(A) the Federal Food and Drug Administration notified the patentee, by letter dated February 20, 1976, that such product's new drug application was not approvable under § 505 (b)(1) of the Federal Food, Drug and Cosmetic Act;

(B) in 1977 the patentee submitted to the Federal Food and Drug Administration the results of a health effects test to evaluate the carcinogenic potential of such product;

(C) the Federal Food and Drug Administration approved, by letter dated December 18, 1979, the new application for such product; and

(D) the Federal Food and Drug Administration approved, by letter dated May 26, 1981, a supplementary application covering the facility for the production of such product.

§ 155A (b) provides that such a restoration will be for five years.

§ 271 (e)(1) deals with infringement of patents and does not fall within the scope of this paper. It allows generic drug companies to use the patented drugs in testing "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." The goal here is to allow them to get approval quicker after expiration of the new drug's extensions.

21 U.S.C. § 355 (j)(4)(D)(i)-(iv) attacks the problems from the FDA side, prohibiting the FDA from approving generics for a varying number of years depending on the length of testing and the novelty of the elements of the drug. A totally new drug can be protected as such for up to ten years, while drugs with active ingredients which have been patented elsewhere can get four, three, or even two years protection depending on their reliance on prior patents.

(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection [enacted Sep. 24, 1984], the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b).

(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to

35 U.S.C. § 154.⁷⁷ However, § 154 cannot casually be applied to drug patents because pharmaceuticals are subject to years of FDA testing prior to approval.⁸

in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of enactment of this subsection and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) for such drug.

(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this subsection [enacted Sept. 24, 1984] and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection [enacted Sept. 24, 1984], the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from the date of enactment of this subsection [enacted Sept. 24, 1984].

See also *Abbott Labs v. Young*, 691 F. Supp. 462 (D.D.C. 1988) remanded for further agency findings, 920 F.2d 984 (D.C. Cir. 1990). However, this section may not be applicable to antibiotic drugs; see *Glaxo, Inc. v. Heckler*, 623 F. Supp. 69 (E.D.N.C. 1985). This section of the Code is commonly known as the Hatch-Waxman Amendments. *Abbott Labs* at 463. The section is considered,

a uniquely legislative evaluation of the benefit of increased availability of generic drugs and the need for continued research for the development of pioneer drugs. Both subsections are part of a coordinated scheme designed to foster these competing interests. Rather than being different their purposes are complimentary.

Abbott Labs at 470. "The evident purpose of the marketing exclusivity provisions is to reward drug manufacturers for substantial expenditures of time and money for the development of pioneer drugs." *Abbott Labs* at 472. 35 U.S.C. § 271, 35 U.S.C. §§ 155, 155A, and 156, and 21 U.S.C. § 355.

⁷⁷ *Eli Lilly and Co. v. Medtronic, Inc.*, 110 S.Ct. 2683, 2688 (1990).

⁸ Patents are designed to promote innovation by providing the right to exclude others from making, using or selling an invention. Patents enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities.

[T]he 1984 Act was designed to respond to two unintended distortions of the 17-year patent term produced by the requirement that certain products must receive premarket regulatory approval. First, the holder of a patent relating to such products would as a practical matter not be able to reap any financial rewards during the early years of the term. When an inventor makes a potentially useful discovery, he ordinarily protects it by applying for a patent at once. Thus, if the discovery relates to a product that cannot be marketed without substantial testing and regulatory approval, the 'clock' on his patent term will be running even though he is not yet able to derive any profit from the invention.

The second distortion occurred at the other end of the patent term. In 1984, the Court of Appeals for the Federal Circuit decided that the manufacture, use, or sale of a patented invention during the term of the patent constituted an act of infringement, . . . even if it was for the sole purpose of conducting tests and developing information necessary to apply for regulatory approval.

Since that activity could not be commenced by those who planned to compete with the patentee until expiration of the entire patent term, the patentee's *de facto* monopoly would continue for an often substantial period until regulatory ap-

Although the patent term in the United States is 17 years, the period during the patent term in which products are marketed (the effective term) is usually less than 17 years because patents often are obtained before products are ready to be marketed.

Effective patent terms are influenced by many factors, including Federal pre-marketing and premanufacturing regulations. The products covered by those regulations include pharmaceuticals, medical devices, food additives, and color additives. Pharmaceuticals, for instance, cannot be marketed in the United States until they have been approved by the Food and Drug Administration (FDA). To obtain such approval, drugs must undergo extensive testing to prove they are both safe and effective. All these products are subject to different regulations that have varying impacts on effective patent terms.

In testimony before several Congressional Committees, representatives from the pharmaceutical firms that are heavily involved in basic research and rely upon patents, claimed that the average effective patent term of drugs has declined. They argued that a continuation of the decline would result in decreased expenditures for research and development and eventually, in a decline in the introduction of new drugs.

As compensation for the loss of patent term due to government review, the research intensive firms argued for patent term extension legislation. They stated that the legislation would create a significant new incentive which would result in increased expenditures for research and developments, and ultimately in more innovative drugs. THE FOOD AND DRUG LAW INSTITUTE, THE LEGISLATIVE HISTORY OF THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984 at 179 (Allan M. Fox, & Alan R. Bennett eds., The Food and Drug Law Institute 1987) (quoting House Report Part I at pp. 17-18) [hereinafter FOX & BENNETT].

proval was obtained. In other words, the combined effect of the patent law and the premarket regulatory approval requirement was to create an effective extension of the patent term.⁹

Section 156, dealing with the first "distortion," is the most important of the Patent Term Restoration Act sections. It allows a human drug product patent to be extended up to five years if

[the product was] subject to a regulatory review period before its commercial marketing or use [and] the permission for the commercial marketing or use of the product after such regulatory review period [was] the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred.¹⁰

Thus § 156 is generally applicable to all new drugs which were subject to FDA testing.

With 35 U.S.C. § 156 and 21 U.S.C. § 355 protecting the drug companies which invent pioneer drugs, and 35 U.S.C. § 271 allowing generic drug companies to quickly begin production when patent extension periods lapse, it is evident that Congress worked a careful compromise between two objectives: encouraging R&D and providing inexpensive drug products for the consumer.¹¹ But note, not all sources supported the legislative acts. "By excluding so many patents from eligibility for term restoration, and by making the eligibility for restoration of some patents turn on circumstances beyond the control of the inventor, the bill falls well short of providing the incentives for innovation that it purports to achieve."¹² Among shortcomings noted were: problems with restoration of a patented drug compound within a previously patented genus; allowing restoration of only first-issued patents (despite Patent and Trademark Office (P.T.O.) requirements of dividing some claims into multiple patents); potential problems of single patent claims by two FDA approved drugs (where only the former may be allowed restoration); and limitations on manufacturing

⁹ *Eli Lilly*, *supra* note 5, at 2688-2689; *See also* FOX & BENNETT, *supra*, at 178, quoting House Report part I at 15.

¹⁰ *Eli Lilly*, *supra* note 5, at 2689, quoting 35 U.S.C. § 156(a); "The Committee established different maximum periods of extensions to provide greater incentive for future innovations. By extending patents for up to five years for products developed in the future, and by providing for up to fourteen years of market exclusivity, the Committee expects that research intensive companies will have the necessary incentive to increase their research and development activities." FOX & BENNETT, *supra* note 8, at 154, quoting House Report Part I, at pages 40-41.

¹¹ *See generally* FOX & BENNETT, *supra* note 8.

¹² *Id.* at 111 (quoting House Report Part I, Minority Views of Rep. Bliley, at 75-6.)

patents, "including the limitation that no other type of patent has been or 'may be issued for any known therapeutic purposes' claiming the method of using the product."¹³

III. DRUG COMPANIES FAIL TO LIVE UP TO THEIR END OF THE BARGAIN

A patent is a monopoly, and when anyone holds a monopoly, that person has the ability or that company has the ability to charge the highest price because there is no one else in competition, and as a matter of public policy, we, under the patent law, give that protection to the person who has put money into research and development for an innovative and new product. But at some point public policy calls for the free market system competition which will bring about the result of a lower price for the consumer.¹⁴

Part of the congressional plan was to protect innovative manufacturers from the ruinous bankruptcy of research, while the rest of the plan was intended to hasten the less expensive generic drugs to the marketplace. Much of this legislation was the result of drug company lobbying and was hailed by both development and generic drug companies alike.¹⁵ However, while the development-drug companies undeniably enjoy the benefit of the congressional enactments, their response has been less than appreciative. The companies' exclusive monopolies have been extended by up to ten years to compensate for loss of profits during FDA testing.¹⁶

¹³ *Id.* The Report continues, "The restrictive eligibility provisions of H.R. 3605 make patent term restoration a haphazard and infrequent event. Innovation is not encouraged when the prospect of meaningful patent life is left to chance and happenstance and when most innovations covered by patents will not be eligible for term restoration." *Id.* at 112.

¹⁴ FOX & BENNETT, *supra* note 8, at 51 (quoting Remarks of Rep. Waxman, House Floor Debate, CONG. REC. H9116 daily ed., Sept. 6, 1984.)

¹⁵ FOX & BENNETT, *supra* note 8, at iv.

Unlike other pieces of legislation . . . where a specific incident, such as the thalidomide tragedy, triggered political pressure for enactment, there was no public outcry for this legislation. Rather, legislation resulted from competing economic groups striking a compromise, taking the compromise to key Senate and House members, and having those members personally involved in the enactment of the legislation.

Id.

¹⁶ The ten-year figure was taken from 21 U.S.C. § 355(j)(4)(D)(i). Though not a "patent" statute (not within 35 U.S.C.), this mandates the FDA's not approving a generic of a totally new drug for ten years. However, this protection period by its terms is only limited to a drug application filed by the date of § 355's enactment. The section more likely to be applied will be 35 U.S.C. § 156, which allows a five year extension (up to a total of 14 years monopoly). 21 U.S.C. § 355 does not extend the patent, but limits FDA approval of generics for a period of time, depending on the novelty of the pioneer drug. It is not all inclusive, as it does not cover antibiotic drugs, etc. See *Glaxo, Inc. v. Heckler*, 623 F. Supp. 69 (E.D.N.C. 1985).

The companies appear to be taking advantage of these statutes and the American public by setting prices which result in unconscionably high profits. This is particularly egregious when the drugs patented are life-saving drugs, and the consumers have little choice but to pay the outlandish prices.¹⁷

IV. THE AIDS DRUG: AN EXTREME EXAMPLE OF ABUSE

Perhaps the clearest example of drug company abuse is the overpriced drug azidothymidine (AZT). This drug, patented by the Burroughs Wellcome company, is a life-extending AIDS remedy which originally sold at a staggering \$10,000 per year.¹⁸ The price is especially impressive in light of the fact that approximately 1.5 million Americans may require the drug on an annual basis.¹⁹ This \$10,000 per year per patient figure was the highest price ever attached to a drug, but the figure appears to be consistent with the growing trend.²⁰ The real problem with this case, though, is that Burroughs Wellcome was directly assisted by the United States government to exploit the American consumers and taxpayers. A columnist for the Washington Post summed the dilemma up succinctly, "What, for example, is owed to the public when it supports, through the government, development of a highly profitable product? And how can the government assure, when it cooperates with private enterprise, protection of the public's need for life-saving drugs at reasonable costs?"²¹

"Burroughs Wellcome, the British multinational pharmaceutical company, stepped forward and in return received generous cooperation from NIH [National Institute of Health] scientists, who tested the drug in the early stages."²² There was little the government could do once it assisted Burroughs in attaining patentability, but it clearly felt that this pricing was a slap in the face, "[a]nd the decision by Burroughs to charge such a high price for AZT has led to important changes in the way government now does business with drug companies."²³

Understandably, Burroughs was entitled to some reward for its cooperation. The company was the first to aggressively move the product into production and it invested \$80 million into what it described as an un-

¹⁷ Mark H. Furstenberg, *AZT: The First AIDS Drug; Who Profits? Who Pays?*, WASH. POST, Sept. 15, 1987 at Z12.

¹⁸ *Id.* See also *Eli Lilly and Co. v. Medtronic, Inc.*, 110 S.Ct. 2683, 2690 n.5 (1990) for examples of excessive prices. This \$10,000 figure has subsequently been reduced to close to \$3000 per year. Malcolm Gladwell, *Lawsuit on AIDS Drug Patent Seeks to End Firm's Monopoly; Patients Cite Federal Scientists' Role in Developing AZT*, WASH. POST, Mar. 20, 1991, at A2.

¹⁹ Furstenberg, *supra* note 17.

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

²³ *Id.* It seems that the government now would contractually reserve rights to patented inventions it has played an active part in developing. But the AZT issue may not yet be dead. See Recent Developments section, *infra*.

certain market.²⁴ They had as many as 700 people working on the drug's development, and scientists involved were required "to work with live AIDS viruses — capable of causing disease if an accident were to occur in the laboratory."²⁵ But the government feels it was taken advantage of, as it had "contributed to Burroughs its entire stock of thymidine, the essential ingredient of AZT" which is "both expensive to make and . . . [is] in short supply."²⁶ In addition, the "government spent \$100,000 a month to distribute the drug. And the government made an incalculably valuable contribution in getting the drug approved quickly and alerting physicians that AZT was available."²⁷ Furthermore, "at \$10,000 per patient per year, Burroughs Wellcome's revenue for the first year of sales will be on the order of \$100 million, exceeding the \$80 million it says it has invested."²⁸ It seems Burroughs Wellcome has shirked its good will responsibility, and left its governmental partner out in the cold. Notes Benjamin Gordon (former staff economist of the Senate Small Business Committee and now with the National Council of Senior Citizens), "Drug companies charge what they can. . . . Whatever the market will bear."²⁹

V. AZT — RECENT DEVELOPMENTS

On March 18, 1991, two HIV-infected men and the People With AIDS Health Group filed a lawsuit in the United States District Court in Washington, D.C., alleging that Burroughs Wellcome's AZT patent should be invalidated because the company "did not conceive, develop or demonstrate the use of the drug in AIDS therapy, and failed to identify federal scientists as the true developers in its patent application."³⁰ Also named in the suit as co-defendant is the United States government, who, plaintiffs claim, was the actual inventor, and could assert rights over the patent.³¹ The suit is being prepared by Public Citizen Health Research

²⁴ Furstenberg, *supra* note 17.

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.* Others have expressed the same sentiment. "The drug companies evidently feel that they can get away with whatever the market will bear." Representative Henry A. Waxman (D. Cal), Andrew Pollack, *The Troubling Cost of Drugs That Offer Hope*, N.Y. TIMES, Feb. 9, 1988, at A1.

³⁰ *Suit Challenges Firm's Patent on AIDS Drug; Pharmaceuticals: The Expensive Treatment AZT is the Only Approved Therapy that Attacks the Virus Directly*, L.A. TIMES, Mar. 20, 1991, BUSINESS, at D2 (Home Ed.). See also M. Snider, *AZT Maker is Target of Suit*, USA TODAY, Mar. 20, 1991, at 1A; *AIDS Drug Patent Challenged in Suit*, N.Y. TIMES, Mar. 20, 1991 (Late Ed.), at A19; M. Gladwell, *supra* note 18; *Lawsuit Seeks to Strip Burroughs Wellcome of AIDS Drug Patent*, WALL ST. J., Mar. 20, 1991; J. Price, *AZT Users File Lawsuit Challenging Its Patent*, WASH. TIMES, Mar. 20, 1991, NATIONAL, at A4; J. Frank, *AIDS Patients Sue Manufacturer of Expensive Anti-AIDS Drug*, REUTERS, Mar. 19, 1991; R. Stein, *Patent for AIDS Drug Challenged*, U. PRESS INT'L, Mar. 19, 1991.

³¹ Stein, *supra* note 31.

Group, the consumer group founded by Ralph Nader.³² The plaintiffs' claim largely is that much of the screening test was done by NIH-funded government scientists, at Duke University and elsewhere, including the National Cancer Institute (N.C.I.).³³ AZT was originally created in 1964 by Jerome Horwicz of the Michigan Cancer Foundation, working on an N.C.I. grant.³⁴ However, Burroughs Wellcome claims that they were the first to discover the vaccine's potential in curing AIDS. Burroughs Wellcome's spokesman, Peter Reese, noted that "some U.S. government scientists offered help, and were involved in the initial screening in the mid-1980's, but AZT's identification as an anti-AIDS drug was the British firm's own."³⁵

³² *Id.*

³³ Price, *supra* note 31.

³⁴ Snider, *supra* note 31.

³⁵ Frank, *supra* note 31. On Mar. 19, 1991, Burroughs Wellcome offered a response to the complaint filed against them. Burroughs Wellcome Co. issued the following:

Recent statements and activities of Public Citizen show little understanding of the complicated processes of drug discovery, development, patents and pricing. "Burroughs Wellcome Co. has addressed these erroneous claims many times in the past and remains confident of its patent position with respect to Retrovir(R) brand zidovudine (AZT)," said Phillip R. Tracy, president and chief executive officer at Burroughs Wellcome. The idea that our company would engage in illegal activities to obtain patent rights is both offensive and wrong. We fully expect to prevail in the lawsuit.

Burroughs Wellcome Response to Public Citizen Action, PR Newswire, Financial News, Mar. 19, 1991.

The company cites the following additional information: Burroughs Wellcome scientists were the first to conceive of the use of the chemical AZT for the treatment of HIV infection in humans. This creative insight is the basis of the "use" patent that the company received in 1988.

Burroughs Wellcome has acknowledged many times the highly skilled collaborative efforts of both government and academic scientists in the subsequent development of this drug. Such work, however, does not entitle the collaborators to be named as co-inventors on any patent.

Attempting now to challenge Burroughs Wellcome's patent on Retrovir, more than five years after its filing, based on ill-conceived notions of the conduct of research and the purpose of patents, could have a chilling effect on innovation in the United States and could discourage further AIDS research.

Burroughs Wellcome's price for a 500-mg dosage regime is \$6 per day (approximately \$2,200 per year), which represents a 70 percent reduction in cost of therapy as a result of price decreases and reduced dosage since the drug was first marketed in 1987.

The company has supported in whole or in part, more than 90 Retrovir-related clinical trials involving some 10,000 patients worldwide. We have provided more than \$40 million worth of AZT to the National Institutes of Health for use in its studies with AZT, including those with potentially competitive therapies.

Burroughs Wellcome has a patient assistance program that temporarily provides Retrovir at no cost to qualified patients until they are able to obtain medication assistance from other sources.

Wellcome has a 110-year heritage of commitment to the improvement of human health through innovative medicines for poorly understood or inadequately treated diseases. Burroughs Wellcome has been more effective in producing tan-

The suit was filed in light of allegations that N.C.I. researchers felt that they should have been named as co-inventors. The researchers met with Burroughs Wellcome for a few months to discuss the issue; suit was filed in light of the fact that an unnamed foreign drug company had expressed its willingness to market the drug at half the price Burroughs Wellcome currently charges.³⁶ The complaint alleges that Burroughs was "less than candid" to the U.S. Patent Office when it failed to reveal that much of the research was done by federally-funded university studies and by the National Institute of Health.³⁷ But it is far from clear that the plaintiffs will make any headway in their suit against Burroughs and the U.S.

Bob Armitage, chief patent counsel for the Upjohn Company, said this is the first case he is aware of in which consumers have tried to strike down a product patent. He said he sees little likelihood this suit will seriously undermine Burroughs Wellcome's patent position on AZT. "Typically, the party that selects particular compounds for testing is the one identified as the inventor, not the party that does the actual screening."³⁸

VI. OTHER MANUFACTURERS ARE CHARGING SIMILARLY PHENOMENAL PRICES

Other drug companies similarly have "taken advantage of consumers who have no alternatives."³⁹ For example,

Tissue plasminogen activator, or TPA, a genetically engineered drug made by Genentech, Inc. for the treatment of heart attacks, costs \$2,200 a dose, 10 times as much as a competitive product not made with the new technology. Human growth hormone, another genetically engineered drug for children who

gible improvement in the lives of patients with HIV than any other single individual or group. In addition to our pioneering work with antiviral medicines, "two common and inexpensive medications (Daraprim® brand pyrimethamine and Septra® brand trimethoprim and sulfamethoxazole) in wide use by AIDS patients today" are among the achievements cited when two Burroughs Wellcome scientists were awarded the Nobel Prize for medicine in 1988.

"Burroughs Wellcome is proud and confident of the contribution it has made to the fight against AIDS, and our commitment to AIDS research and people with HIV infection continues", Tracy said. *Id.*

³⁶ Gladwell, *supra* note 18.

³⁷ Frank, *supra* note 31.

³⁸ Price, *supra* note 31. Though it might be beneficial to use Burroughs to make an example that excessive pharmaceutical charges for life-saving drugs will not be tolerated, it seems unlikely (from the allegations of the complaint) that the complainants have any legal recourse here.

³⁹ Andrew Pollack, *The Troubling Cost of Drugs That Offer Hope*, N.Y. TIMES, Feb. 9, 1988, at A1.

are dwarfs that is made by Genetech and Eli Lilly and Company, can cost from \$8000 to more than \$30,000 a year. And Merck's hepatitis B vaccine, the first vaccine made by genetic engineering, sells for \$120 a treatment, higher than most vaccines and out of the reach of developing nations, where the disease is prevalent.⁴⁰

VII. OTHER EXAMPLES

"Merck's new cholesterol-reducing drug, called Lovastatin, can cost \$600 a year and up to \$3,000 in severe cases. And some advanced antibiotics cost three times as much as older products."⁴¹

And finally,

The Armour Pharmaceutical Company introduced a major drug . . . the first blood-clotting factor for hemophiliacs made using the tools of biotechnology. This purer version of Factor VIII virtually eliminated any chance that hemophiliacs would contract AIDS, hepatitis or other diseases from treatment.

There was one catch: This high-tech drug costs five to eight times as much as older versions, bringing the cost of a year supply to more than \$25,000. That puts the drug out of the reach of many patients for whom it is a matter of life and death.⁴²

There is clearly a problem with a system which rewards industry with such a windfall, to the detriment of the ill and dying. Industry critics insist that the companies' need for profits must be balanced with the medical needs of the patients.⁴³ Drug corporations defend themselves on grounds that R&D is such a risky venture that they have huge expenses to recoup when they finally go to market. Others insist that much of the profits will be funnelled back into R&D for other new disease cures.⁴⁴

⁴⁰ *Id.* See also *Eli Lilly and Co. v. Medtronic, Inc.*, 110 S.Ct. 2683, 2690 (1990). According to one source, a year's dosage of Cyclosporine (used to suppress rejection of new organs) costs from \$5,000 to \$7,000; of AZT (used to treat AIDS) \$8,000; of Monoclate (used to speed blood clotting in hemophiliacs) \$25,000 and of Growth Hormone (used to treat dwarfism) \$8,000 to \$30,000 Another new drug, Tissue Plasmogen Activator, used in the treatment of heart attacks to dissolve blood clots, costs \$2,200 per dose, and is prescribed for only a single dose.

Id. Such examples are merely illustrative, there are likely many more overpriced drugs filling the marketplace.

⁴¹ Pollack, *supra* note 40.

⁴² *Id.*

⁴³ *Id.* These critics seem to feel such balancing cannot be done at the industry level, where financial motives can be too easily shielded by excuses and justifications; such evaluations need to be done at a governmental level.

⁴⁴ *Id.* quoting R. Swanson, president of Genentech Inc.

Still others defend on the claim that "even expensive drugs can save money over all by keeping people out of the hospital, or making surgery unnecessary."⁴⁵ Another reason for the high prices is that "[t]he rapid advance of technology is also spurring companies to try to recover their costs faster."⁴⁶

Industry analysts, however, claim that the *main* factor in the extreme over-pricing is not so much the increased costs of R&D, but the fact that "companies base their prices on the value of the drug to consumers and not the cost."⁴⁷ Thus, the more imperative it is to a patient that he gets the medication, the more he will have to pay. This often results in what Richard Kessel, Executive Director of the New York State Consumer Protection Board, describes as "closing out people from the only drug that is available."⁴⁸

VIII. THE COSTS AND TESTING TIMES FOR DRUGS

It would be remiss to talk about high prices without an examination of the costs involved. When the 1984 Acts for Extension of Drug Patent Lives were lobbied for, drug companies specified the average period of time required to recoup the investment of the development of a new drug. Congress considered this in light of the average and extreme periods of time a drug could be hung up in FDA testing, plus the loss of profits once generic companies were allowed into the market.⁴⁹

To be fair, the amounts the drug companies charge may have some basis in the reality of the business. "Estimated total costs of R&D required up through FDA marketing approval of a new drug were \$70 million and climbing in 1981, as opposed to \$4 million in 1962."⁵⁰

Because a patent continues to toll when a manufacturer is testing and awaiting government approval, the amount of patent time remaining after the approval is less than the normal 17 years. For example, representatives of the drug industry

⁴⁵ *Id.* quoting John Doorley, a Merck & Company spokesman.

⁴⁶ *Id.* Presumably companies need to charge more because the pace of the competition is so much faster that a company needs ready capital to invest in the next area of research as soon as they can recoup what was spent in the previous area. Possibly what is meant by this is that companies need to employ new tests and buy state of the art equipment to keep pace and such can be an expensive endeavor. See also, *Eli Lilly and Co. v. Medtronic, Inc.*, 110 S.Ct. 2683, 2695 (1990) ("Although the Court gives examples of high cost drug dosages, it does not demonstrate that the testing of these drugs detracts from a patent holder's sales.")

⁴⁷ Pollack, *supra* note 40.

⁴⁸ *Id.*

⁴⁹ FOX & BENNETT, *supra* note 8.

⁵⁰ Brand, *supra* note 1.

have testified that the average patent time left after approval is between 8 and 10 years. Research-intensive firms predict that declining patent terms will result in the development of fewer innovative products.⁵¹

Other journalists have also noted the extreme time limits and expenses a drug manufacturer must face.

At the beginning of the 1960's, before the amendments [1962 of the FDCA] were passed, it took two and a half years, on average, to bring a new product from the laboratory to the marketplace. Today [in 1978] a drug company can spend as much as ten years getting the required approval of the Food and Drug Administration. In consequence, the cost of introducing a new drug has skyrocketed, from about \$1.5 million in 1960 to perhaps \$15 million.⁵²

⁵¹ FOX & BENNETT, *supra* note 8, at 181, quoting Remarks of Rep. Waxman, Cong. Record of Aug. 8, 1984 at H8706. See also Brand, *supra* note 1, at 494, which states,

Patents still nominally confer the same rights on their holders and have the same nominal life of seventeen years. There is evidence, however, that the expected value and effective life of a patent lies in conferring upon the owner the rights to a legal monopoly on the sale of the product and the hope of a de facto monopoly even after expiration. As noted above, however, increased competition from generics is rapidly diminishing this latter phenomenon.

Of course, the economic profits from discovery of a patentable drug cannot be reaped until it is offered for sale. Therefore, the benefits of a patent do not accrue until the drug is approved by the FDA. However, . . . the right to enter the commercial market is not and should not be concomitant with a patent grant, which gives only exclusive selling rights when and if the drug is approved for marketing. As the standards for FDA approval and patenting are divergent, there may be a significant time lag between the grant of a patent and the time when sufficient evidence of safety and efficacy has been accumulated to satisfy FDA's stringent requirements, and consequently to realize the value of the patent.

It has been found that the effective life of a pharmaceutical patent has in fact fallen from 16.5 years in 1960 to 9.7 years in 1978. In light of this evidence, it is no wonder that firms are investing less in pharmaceutical R&D. The expected return from a patent is much lower, especially considering the increased introduction of generic drugs into the market upon expiration of the patent. Studies have also shown that in order for a manufacturer to break even and just cover R&D costs involved in marketing a new drug, he would have to market the drug exclusively for 12 to 19 years. The conclusion in this economic analysis depends upon the interest rate, since that rate determines the 'opportunity cost' of the funds for R&D and, thus, the break-even level. At a ten percent market interest rate, a new drug manufacturer will proceed with necessary R&D if he can expect a nineteen-year product market life. As indicated above, effective pharmaceutical patent life now falls nearly ten years short of that break-even point. *Id.*

⁵² Linda Snyder, *Prescribing for the Drug Stocks*, FORTUNE, Jan. 30, 1978, at 121.

Also, it takes an average of about eight years to get a drug from the laboratory bench to the drug store shelf. About six of those years are spent on tests— first on animals, then on humans. The rest of the time is taken up with the bureaucratic processing of a drug by national regulatory authorities.

The cost of developing a new medicine in America was put at \$74 million in 1980. Companies say the figure is now [in 1984] nearly \$100 million. Inventors' patents give them a head start over the generic manufacturers to help them recover that cost and to make a (sometimes huge) profit. In theory, the life of a patent in the United States is 17 years (unchanged since 1861) and of a patent in Europe is 20 years. In practice, after regulatory delays the effective patent life of a new drug in America is more like 9.5 years. This dipped as low as 7.5 years in 1980.⁶³

Thus it might be argued that the five-year patent extension of § 156 is insufficient to recompense the developer for the period of up to ten years lost on FDA testing. And with § 271 enabling generic drug companies to get up to speed faster, it is less likely that the drug companies will always recoup the hundreds of millions they have sunk into R&D. But even with the great costs involved, and the fact that in some situations the extension given to balance the lengthy FDA tests is not long enough, it must be remembered that Congress meant the 1984 Act as a compromise. The goal was not only to protect drug companies who develop new products, but also to get cheaper drugs out to the consumers. And in situations like Burroughs' AZT, where the company more than recouped their investment in the first year, there really is no acceptable argument.

IX. PROBLEMS CAUSED BY ALLOWING DRUG COMPANIES TO PATENT LIFE-SAVING DRUGS

The potential problems with allowing drug manufacturers to patent life-saving drugs are three-fold. First, many drug companies seem to be pushing prices to the limit that the market can bear. One should note that the goal of a patent is not solely to reward an inventor, but to get inventions of value to the public quicker.⁶⁴ In this light it might seem

⁶³ Business Brief, *Testing Time for Drugs*, THE ECONOMIST, Aug. 7, 1982, at 75. Though these articles are all pre-1984 act, they help to understand the great expense and lengthy FDA time losses involved. It is likely both the expense and testing times have continued their dramatic escalation.

⁶⁴ "[W]e must bear in mind that it was not alone to reward the inventor that the patent monopoly was granted. The public was to get its reward and have the advantage of the inventors discovery as early as was reasonably possible." *Hull v. Davenport*, 90 F.2d 103, 105 (C.C.P.A. 1937).

unreasonable to give a patent (and/or extension) to a company who prices a drug such that it remains largely out of reach of the public. More importantly, it seems impractical to give an exclusive license on something that people can, literally, not live without.⁵⁵ Because of the demand, the companies really can price the drugs as high as they want, and there will still be buyers— as evidenced by the obscene prices of drugs such as AZT, Cyclosporine, Monoclate etc. Such corporate conduct is probably costing the lives of many of those who cannot afford the drugs.

Second, there is a danger of drug suppression. While no cases of this are cited, it is possible that a drug company given a monopoly advantage would be on the forefront of technology in the field and would withhold even newer technology until the first patent's expiration. Where companies are given such advantages and encouragement to pioneer a field such as that of pharmaceuticals, the danger of suppression exists, especially where the government assists companies like Burroughs Wellcome (re: AZT) to become so far ahead of the pack - that it is likely such a company could safely sit on an AZT "II" until the monopoly period given on the original AZT runs out. This may not be a serious concern with ordinary consumer products, but withholding of drugs can literally be a matter of life and death.⁵⁶

Finally, the high costs of these drugs are driving up the cost of medicine in general. Medicaid and Medicare can only cover so much, and thus if indigents are to get the drugs, and cannot afford them, the costs will naturally be passed on to other medical consumers. If the drug companies are receiving tens of thousands of dollars for these drugs per user, it is easy to see how the total cost will accumulate.

Drug companies will cite the excuse that R&D is an expensive and risky venture, that they need a substantial number of years to recoup their expenses, and that, even with the new FDA excess exclusivity periods, they are not made whole.⁵⁷ As scientific understanding improves,

⁵⁵ Though not covered within the scope of this paper, the same argument holds true for many life-preserving patented medical devices, such as artificial hearts, limbs, iron lungs, dialysis machinery etc. Potential differences may exist if these devices are bought outright (rather than by dosage), if brand loyalty is significantly less, or if such devices command any resale value.

⁵⁶ *But cf.* HARRY AUBREY TOULMIN, *PATENTS AND THE PUBLIC INTEREST* 65 (1939), which says it is likely that this does not happen.

You hear the charge frequently made that the most valuable inventions which are covered by patents are deliberately suppressed and not put on the market. Usually these patents are said to be in the hands of very large companies who have ample financial resources to merchandise these inventions.

Precisely the reverse is true. If it were not for patents, we would have suppression of ideas and new developments because there would be no encouragement to develop these new things to force manufacturers out of the rut.

Id.

⁵⁷ See Brand, *supra* note 1. See also Pollack, *supra* note 40.

the FDA testing becomes more detailed, expensive, and the tests even more numerous and lengthy. The drug companies will also argue that since the new FDA laws allow the generics to get up to speed quicker when the exclusivity period lapses, profits reaped by the developers during the exclusivity period may be the researching companies' last. This has been viewed with skepticism, in light of the phenomenal amounts being charged, and the durability of drug company brand name strengths.⁵⁸

X. CONCLUSION: POSSIBLE GOVERNMENTAL SOLUTIONS

It thus is justifiable to argue that maybe patenting is not a good idea in the area of life-saving pharmaceuticals. The most drastic solution, of course, would be to disallow patenting of drugs deemed "life-saving." This might present more problems than are resolved, as it would require administrative determination of which drugs fall into such a category. And unless other incentives replace that of an exclusive monopoly, there will be few attempts to discover or reveal such new drugs.

There are several other options available in order to preserve research intensive efforts and get new drugs cheaply to consumers. One possibility is to use government grants as incentives, funding the life-saving drug research within academic institutions and humanitarian foundations, rather than in the private sector. Such academic laboratories might be better in tune with public needs, targeting the most dangerous (rather than the most widespread) of diseases, and enhancing funding in this area might prove a solution.

⁵⁸ It is clear that a drug company's brand name is often more durable than the patent itself. Doctors, accustomed to prescribing a specific brand during the years of protection, continue to use that name even after cheaper versions enter the market. "There is increased public interest in what are called 'generic prescriptions', i.e., getting doctors to eschew brand-name drugs when they prescribe, instead specifying products that are chemically and therapeutically equivalent — and much cheaper. Today, only about 12 percent of all new prescriptions are written generically." Snyder, *Prescribing for the Drug Stocks*, *FORTUNE*, Jan. 30, 1978 at 121. "Further, although a patent nominally expires after seventeen years, large manufacturers have often held de facto monopolies for much longer periods of time. This is due largely to their ability during the period of patent effectiveness to create strong brand loyalties in physicians, pharmacists, and consumers." Brand, *supra* note 1, at 493.

In addition, it is often the case that the new generic drugs do not replace, but merely supplement the older drug versions, hence creating long periods of product profitability.

Nor is AZT likely to be replaced in the near future by another drug. Although another drug is being tested, and a third is on the way, it will be some time, two years perhaps, before those drugs can be brought to market And anyway, 'new drugs' . . . 'are extremely likely to be used in combination with AZT. We'll use combinations of drugs to the best effect, just as we do in other chemotherapies'.

Furstenberg, *supra* note 17, at 212.

Note also the Sandoz case, where a company was attempting to tie up drug time by leaguering itself with a drug servicing company. ANTITRUST AND TRADE REG. REP., *supra* note 4.

Another possibility is to place a cap legislatively on prices which may be charged for drugs, perhaps tied to the actual expense put into the research (divided by the number of potential consumers).⁵⁹ Research might then be enhanced by government bonuses for lifesaving drugs. Alternatively, the system can be pushed totally into the realm of socialism and governmental paternalism, with the government contracting as a go-between between the drug companies and consumers: buying the drugs "wholesale," and retailing them to the consumers at a loss.⁶⁰

The ultimate problem is that Congress has extended monopolies for the benefit of R&D intensive companies; companies which in return have "bitten the hand that feeds them" by charging unreasonably high prices. Even if "lifesaving-drug" companies should be allowed to patent their inventions, a strong argument can be made that patent extensions, under 35 U.S.C. § 156, should not be granted. This is because the drug development companies, by pricing the drugs so expensively, are using the initial of the "twin aims" of Congress, rewarding invention, to nullify the effects of the latter.⁶¹ While the second aim was to accelerate entry into the market of generic drugs, and thus foster reduced prices for consumers, it clearly was not meant to enable the drug development companies to maximize their profits during the monopoly period. Congress had the goal of the *consumer* in mind throughout the reform. The objectives were to encourage drug companies to invent and to get the drugs to the market cheaper. Though the legislation was billed as a compromise position between the two types of drug companies, it is clear that the consumer was meant to be the real winner. Congress never intended to force the American consumer into a choice between death or financial ruin.

⁵⁹ Congress might eventually pass laws to restrain prices[,] . . . [b]ut there does not appear to be much sentiment in Washington for regulation of drug prices, something that is done in many other countries. Still, analysts say, if the Government begins paying for drugs through Medicare, it will begin putting pressure on drug companies to lower prices. That would be the first step toward price controls.

Pollack, *supra* note 40.

⁶⁰ It should be noted that many corporations have been beginning to buy some drugs wholesale as part of their health plans. "Some corporate health plans are beginning to buy drugs in bulk for employees." Pollack, *supra* note 40. Also relevant is that the government has now set up a fund for those who need AZT, which Medicaid cannot afford to cover. "Some states are paying for AZT through Medicaid. Private health insurers are beginning to pay for it. Congress has created a \$30 million fund so that people who need it can get it." Furstenberg, *supra* note 17. But not all states can afford to subsidize AZT. In California, the maximum income eligibility bracket for free AZT was recently moved from \$44,000 per year down to \$26,540. Elaine Herscher, *New AIDS Law Cuts Eligibility for Free Drugs*, SAN FRANCISCO CHRON., Mar. 19, 1991, at A5.

⁶¹ See *infra* note 11, at 7, 35 U.S.C. §§ 156, and 355, patent extension provisions, were added along with the compromise statute 35 U.S.C. § 271, which allows generic drug companies to get FDA approval, and hence to the market, quicker.

The optimal solution would be for drug companies to price life-saving products reasonably. Though they clearly will receive whatever amount they choose to charge for such wares, it is likely large companies could still be profitable with substantially lower prices, as the market of those who could afford the product would correspondingly increase. While moralistic pleas and humanitarian attitudes have no place in a free market economy, the drug manufacturers should reform, or it is possible that the pricing of drugs may (and perhaps should) be legislatively taken out of their hands altogether.

